

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tsai et al.  
Serial No. : *Not yet Assigned*  
Filed : *Herewith*  
Title : METHOD FOR TREATING NEUROPSYCHIATRIC DISORDERS

Art Unit : Unknown  
Examiner : Unknown

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

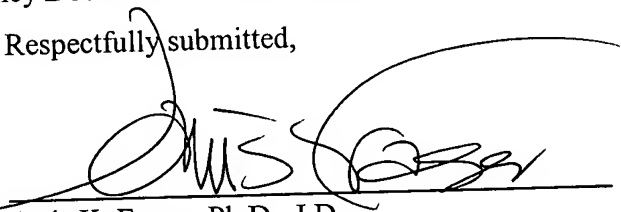
Under 35 USC §120, this application relies on the earlier filing date of Application Serial No. 09/291,296, filed April 14, 1999, now U.S. Patent No. 6,228,875; Application Serial No. 09/834,351, filed April 13, 2001, now U.S. Patent No. 6,420,351; and Application Serial No. 10/196,686, filed July 15, 2002. The references listed on the enclosed form PTO-1449 were submitted to and/or cited by the Office in the prior applications and/or in U.S. Application Nos. 90/006,227 and 90/006,532, the two pending reexamination applications of U.S. Patent No. 6,228,875. The cited references are therefore not provided in this application.

This statement is being filed with the application. Please apply any charges or credits to Deposit Account No. 06-1050, referencing attorney Docket No. 13785-745005.

Respectfully submitted,

Date:

*Sept. 23, 2003*

  
Janis K. Fraser, Ph.D., J.D.  
Reg. No. 34,819

Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110-2804  
Telephone: (617) 542-5070  
Facsimile: (617) 542-8906

20728573.doc

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EL 983 022 615 US

September 23, 2003  
Date of Deposit

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 13785-745005	Application No. Not yet Assigned
	Applicant Tsai <i>et al.</i>			
	Filing Date Herewith		Group Art Unit Unknown	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3,873,722	3/25/1975	Smythies			
	AB	5,015,740	05/14/1991	Kennis <i>et al.</i>			
	AC	5,051,448	09/24/1991	Shashoua			
	AD	5,061,721	10/29/1991	Cordi <i>et al.</i>			
	AE	5,112,863	05/12/1992	Hashimoto <i>et al.</i>			
	AF	5,187,171	02/16/1993	Cordi			
	AG	5,260,324	11/9/1993	Cordi <i>et al.</i>			
	AH	5,468,763	11/21/1995	Cordi <i>et al.</i>			
	AI	5,482,967	01/09/1996	Natsugari <i>et al.</i>			
	AJ	5,633,281	05/27/1997	Teall <i>et al.</i>			
	AK	5,837,730	11/17/1998	Javitt			
	AL	5,854,286	12/29/1998	Javitt <i>et al.</i>			
	AM	6,162,827	12/19/2000	Javitt			
	AN	6,355,681	03/12/2002	Javitt			
	AO	6,361,957	03/26/2002	Javitt			
	AP	US2002/0161048 A1	10/31/2002	Javitt			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AQ	0 387 867 A1	09/19/90	Europe			XX	
	AR	0 432 039 A2	06/12/91	Europe			XX	
	AS	0 652 012 A1	05/10/95	Europe			XXX	
	AT	0 696 586 A1	02/14/96	Europe			XX	
	AU	JP 08026986A	01/30/96	Japan			XX	
	AV	JP 55 020747 A	02/14/80	Japan (Abstract)			XX	
	AW	DE 41 17 629 A1	12/03/92	Germany				XX

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13785-745005	Application No. Not yet Assigned
	Applicant Tsai <i>et al.</i>		
	Filing Date Herewith	Group Art Unit Unknown	

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AX	RU 2096044 C1	11/20/97	Russia			XX	
	AY	HU P9200192A	01/27/03	Hungary				XX
	AZ	WO 89/05144	06/15/89	PCT			XX	
	AAA	WO 97/20552	06/12/97	PCT			XX	
	ABB	WO 97/20553	06/12/97	PCT			XX	
	ACC							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	ADD	Barnes <i>et al.</i> , "A Rating Scale for Drug-Induced Akathisia" <i>British Journal of Psychiatry</i> 154:672-676, 1989.
	AEE	Bart <i>et al.</i> , "Efficacy and Tolerance of D-Cycloserine in Drug-Free Schizophrenic Patients" <i>Biological Psychiatry</i> 40:1298-1300, 1996.
	AFF	Baxter <i>et al.</i> , "D-Cycloserine, a Novel Cognitive Enhancer, Improves Spatial Memory in Aged Rats" <i>Neurobiology of Aging</i> 15:207-213, 1994.
	AGG	Baxter <i>et al.</i> , "Modulation of the NMDA Receptor Complex by D-Cycloserine" <i>CNS Drug Reviews</i> 1:74-90, 1995.
	AHH	Cascella <i>et al.</i> , "d-Cycloserine adjuvant therapy to conventional neuroleptic treatment in schizophrenia: an open-label study" <i>Journal of Neural Transmission</i> 95:10-111, 1994.
	AII	Chessell <i>et al.</i> , "D-Cycloserine, a putative cognitive enhancer, facilitates activation of the N-methyl-D-aspartate receptor-ionophore complex in Alzheimer brain" <i>Brain Research</i> 565:345-348, 1991.
	AJJ	Contreras, "D-Serine Antagonized Phencyclidine- and MK-801-Induced Stereotyped Behavior and Ataxia" <i>Neuropharmacology</i> 29:291-293, 1990.
	AKK	Crane, "Cycloserine as an Antidepressant Agent" <i>The American Journal of Psychiatry</i> 115:1025-1026, 1959.
	ALL	Cutler <i>et al.</i> , "The Tolerability and Efficacy of Cycloserine in Alzheimer's Disease" <i>Am. Coll. Neuropsychopharmacol. Annual Meeting</i> , Puerto Rico, 1994.
	AMM	D'Souza <i>et al.</i> , "Glycine Site Agonists of the NMDA Receptor: A Review" <i>CNS Drug Reviews</i> 1:227-260, 1995.
	ANN	Falk <i>et al.</i> , "A Case Series of D-Cycloserine Added to Donepezil in the Treatment of Alzheimer's Disease" <i>J. Neuropsychiatry Clin. Neurosci.</i> 14:466-467, 2002.
	AOO	Fishkin <i>et al.</i> , "D-Cycloserine Attenuates Scopolamine-Induced Learning and Memory Deficits in Rats" <i>Behavioral and Neural Biology</i> 59:150-157, 1993.
	APP	Francis <i>et al.</i> , "A Glycine Site as Therapeutic Target" Institute of Neurology, Miriam Marks Department of Neurochemistry; London, WC1N, 1PJ, United Kingdom, pp. 184-188.
	AQQ	Goff <i>et al.</i> , "D-Cycloserine Added to Clozapine for Patients With Schizophrenia" <i>Am. J. Psychiatry</i> 153:1628-1630, 1996.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13785-745005	Application No. Not yet Assigned
	Applicant Tsai <i>et al.</i>		
	Filing Date Herewith	Group Art Unit Unknown	

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	ARR	Goff <i>et al.</i> , "Dose-Finding Trial of D-Cycloserine Added to Neuroleptics for Negative Symptoms in Schizophrenia" <i>Am. J. Psychiatry</i> 152:1213-1215, 1995.
	ASS	Hashimoto <i>et al.</i> , "D-Alanine inhibits methamphetamine-induced hyperactivity in rats" <i>European Journal of Pharmacology</i> 202:105-107, 1991.
	ATT	Javitt <i>et al.</i> , "Glycyldodecylamide, a phencyclidine behavioral antagonist, blocks cortical glycine uptake: implications for schizophrenia and substance abuse" <i>Psychopharmacology</i> 129:96-98, 1997.
	AUU	Javitt <i>et al.</i> , "Reversal of Phencyclidine-Induced Hyperactivity by Glycine and the Glycine Uptake Inhibitor Glycyldodecylamide" <i>Neuropsychopharmacology</i> 17:202-204, 1997.
	AVV	Kay <i>et al.</i> , "The Positive and Negative Syndrome Scale (PANSS) for Schizophrenia" <i>Schizophrenia Bulletin National Institute of Mental Health</i> 13:261-276, 1987.
	AWW	Kirkpatrick <i>et al.</i> , "The Schedule for the Deficit Syndrome: An Instrument for Research in Schizophrenia" <i>Psychiatry Research</i> 30:119-123, 1989.
	AXX	Kumashiro <i>et al.</i> , "Free D-serine in post-mortem brains and spinal cords of individuals with and without neuropsychiatric diseases" <i>Brain Res.</i> 681:117-125, 1997.
	AYY	Leiderman <i>et al.</i> , "Preliminary Investigation of High-Dose Oral Glycine in Serum Levels and Negative Symptoms in Schizophrenia: An Open-Label Trial" <i>Biological Psychiatry</i> , 39:213-215, 1996.
	AZZ	Lindenmayer <i>et al.</i> , "Five-Factor Model of Schizophrenia Initial Validation" <i>The Journal of Nervous and Mental Disease</i> 182:631-638, 1994.
	AAAA	Lingjaerde <i>et al.</i> , "The UKU side effects rating scale" <i>Scandinavian Society of Psychopharmacology Committee of Clinical Investigations (UKU)</i> ; pp. 81-94, 1986.
	ABBB	Malhotra <i>et al.</i> , "NMDA receptor function and human cognition the effects of ketamine in healthy volunteers" <i>Neuropsychopharmacology</i> 14:301-307, 1996.
	ACCC	Matsuoka <i>et al.</i> , "D-Cycloserine, a Partial Agonist at the Glycine Site Coupled to N-Methyl-D-aspartate Receptors, Improves Visual Recognition Memory In Rhesus Monkeys" <i>The Journal of Pharmacology and Experimental Therapeutics</i> 278:891-897, 1996.
	ADDD	McKhann <i>et al.</i> , "Clinical diagnosis of Alzheimer's disease: Report of the NINCDS-ADRDA Work Group under the auspices of Department ..." <i>Neurology</i> 34:939-944, 1984.
	AEEE	Monahan <i>et al.</i> , "Characterization of a [ <sup>3</sup> H]Glycine Recognition Site as a Modulatory Site of the N-Methyl-D-Aspartate Receptor Complex" <i>Journal of Neurochemistry</i> 53:370-375, 1989.
	AFFF	Morrison and Boyd, "Carboxylic Acids," Chapter 23, pp. 822-823, in <i>Organic Chemistry</i> , Fifth ed. Boston: Allyn and Bacon, Inc.
	AGGG	Nilsson <i>et al.</i> , "Glycine and D-serine decrease MK-801-induced hyperactivity in mice" <i>J. Neural. Transm</i> 104:1195-1205, 1997.
	AHHH	Nishikawa <i>et al.</i> , "PCP-induced abnormal behavior and c-fos gene expression in the brain as indices for neuroleptic-resistant symptoms of schizophrenia" <i>Folia Pharmacologica Japonica</i> , Patent Abstract XP-002117995, 1996.
	AIII	Papp <i>et al.</i> , "Antidepressant-like effects of 1-aminocyclopropanecarboxylic acid and D-cycloserine in an animal model of depression" <i>European Journal of Pharmacology</i> 316:145-151, 1996.
	AJJJ	Patent Abstract; XP-002117996; JP55020747 A; "Antidepressant Drug Low Side Effect Contain Serine Salt Effect Component" 1980.
	AKKK	Patent Abstract; XP-002117997; JP08026986; "Anti-phencyclidine drugs contain D-serine esters of formula (I) or their salts as active agents" 1996.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary)  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13785-745005	Application No. Not yet Assigned
	Applicant Tsai <i>et al.</i>		
	Filing Date Herewith	Group Art Unit Unknown	

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	ALLL	Prous <i>et al.</i> , "D-Cycloserine" <i>Drugs of the Future</i> 19: 988-991, 1994.
	AMMM	Ramakers <i>et al.</i> , "The Impaired Long-Term Potentiation in the CA1 Field of the Hippocampus of Cognitive Deficient Microencephalic Rats is Restored by D-Serine" <i>Neuroscience</i> 54:49-60, 1993.
	ANNN	Ramakrishna <i>et al.</i> , "Betaine reverses toxic effects of aluminium: Implications in Alzheimer's disease (AD) and AD-like pathology" <i>Current Science</i> 75:1153-1156, 1998.
	AOOO	Randolph <i>et al.</i> , "D-Cycloserine Treatment of Alzheimer Disease" <i>Alzheimer Disease and Associate Disorders</i> 8:198-205, 1994.
	APPP	Riekkinen <i>et al.</i> , "The Effects of D-Cycloserine on Cognition in Experimental Models of Alzheimer's Disease" <i>Neurology</i> 43:A292; Abstract XP-0021178979.
	AQQQ	Rimland, "Dimethylglycine (DMG), a nontoxic metabolite, and autism"; <i>Editor's Notebook</i> ; Abstract XP-002117993.
	ARRR	Rockstroh <i>et al.</i> , "Effects of the Novel NMDA receptor antagonist SDZ EAA 494 on memory and attention in humans" <i>Psychopharmacology</i> 124:261-266, 1996.
	ASSS	Rosen <i>et al.</i> , "A new rating scale for Alzheimer's Disease" <i>The American Journal of Psychiatry</i> 141:1356-1364, 1984.
	ATTT	Russell, "A Multiple scoring method for the assessment of complex memory functions" <i>Journal of Consulting and Clinical Psychology</i> 43:800-809, 1975.
	AUUU	Schuster <i>et al.</i> , "D-Cycloserine reverse the working memory impairment of hippocampal-lesioned rats in a spatial learning task" <i>European Journal of Pharmacology</i> 224:97-98, 1992.
	AVVV	Simeon <i>et al.</i> , "d-Cycloserine Therapy of Psychosis by Symptom Provocation" <i>Comprehensive Psychiatry</i> 11:80-88, 1970.
	AWWW	Simpson <i>et al.</i> , "A Rating Scale for Extrapyrarnidal Side Effects" <i>Acta Psychiatr. Scand. Suppl.</i> 212:11-19, 1970.
	AXXX	Sirvio <i>et al.</i> , "D-Cycloserine, a modulator of the N-methyl-D-aspartate receptor, improves spatial learning in rats treated with muscarinic antagonist" <i>Neuroscience Letters</i> 146:215-218, 1992.
	AYYY	Tanii <i>et al.</i> , "Effects of Allosteric Agonists for NMDA Receptor and Their Derivatives on PCP-Induced Abnormal Behaviors in Rat" National Institute of Neuroscience, NCNP, Kodaira; XP-002117991; Vol. 44, 1990.
	AZZZ	Tanii <i>et al.</i> , "Stereoselective Antagonism by Enantiomers of Alanine and Serine of Phencyclidine-Induced Hyperactivity, Stereotypy and Ataxia in the Rat" <i>The Journal of Pharmacology and Experimental Therapeutics</i> 269:1040-1048, 1994.
	AAAAA	Temple <i>et al.</i> , "Chronic, post-injury administration of D-cycloserine, an NMDA partial agonist, enhances cognitive performance following experimental brain injury" <i>Brain Research</i> 741: 246-251, 1996.
	ABBBB	Tsai <i>et al.</i> , "A Preliminary Study of D-Cycloserine Treatment in Alzheimer's Disease" <i>The Journal of Neuropsychiatry</i> 10:224-226, 1998.
	ACCCC	Tsai <i>et al.</i> , "Improved cognition in Alzheimer's Disease with Short-Term D-Cycloserine Treatment" <i>Am. J. Psychiatry</i> 156:467-469, 1999.
	ADDDD	Vamvakides, "Nootropic activity of glycinergic derivatives in relation to their dualistic effects on cerebral monoamines" <i>Boll. Chim. Farm.</i> 133:369-373, 1994.
	AEEEE	van Berckel <i>et al.</i> , "Efficacy and tolerance of D-cycloserine in drug-free schizophrenic patients" <i>Biol. Psychiatry</i> 40:1298-1300, 1996.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	